

BEFORE THE DEPARTMENT OF PUBLIC  
HEALTH AND HUMAN SERVICES OF THE  
STATE OF MONTANA

In the matter of the adoption of New	)	NOTICE OF ADOPTION
Rules I through XXX and the repeal of	)	AND REPEAL
ARM 37.112.101, 37.112.105,	)	
37.112.106, 37.112.107, 37.112.112,	)	
37.112.113, 37.112.114, 37.112.120,	)	
37.112.122, 37.112.124, 37.112.126,	)	
37.112.128, 37.112.130, 37.112.135,	)	
37.112.136, 37.112.140, 37.112.143,	)	
and 37.112.146 pertaining to tattooing	)	
and body piercing	)	

TO: All Interested Persons

1. On October 5, 2006, the Department of Public Health and Human Services published MAR Notice No. 37-392 pertaining to the public hearing on the proposed adoption and repeal of the above-stated rules, at page 2339 of the 2006 Montana Administrative Register, issue number 19.

2. The department has adopted New Rules I (37.112.102), III (37.112.108), IV (37.112.109), V (37.112.115), VI (37.112.116), VII (37.112.117), VIII (37.112.121), IX (37.112.125), X (37.112.129), XIV (37.112.137), XV (37.112.141), XVI (37.112.142), XVIII (37.112.147), XIX (37.112.150), XX (37.112.151), XXII (37.112.153), XXIV (37.112.157), XXV (37.112.158), XXVI (37.112.159), XXVII (37.112.162), XXVIII (37.112.163), XXIX (37.112.165), and XXX (37.112.167) as proposed.

3. The department has repealed ARM 37.112.101, 37.112.105, 37.112.106, 37.112.107, 37.112.112, 37.112.113, 37.112.114, 37.112.120, 37.112.122, 37.112.124, 37.112.126, 37.112.128, 37.112.130, 37.112.135, 37.112.136, 37.112.140, 37.112.143, and 37.112.146 as proposed.

4. The department has adopted the following rules as proposed with the following changes from the original proposal. Matter to be added is underlined. Matter to be deleted is interlined.

RULE II (37.112.103) DEFINITIONS (1) through (21) remain as proposed.

(22) "Sharps" means ~~the definition found in 75-10-1003, MCA~~ any discarded instrument or article that may be contaminated with blood or other bodily fluid and may cause punctures or cuts, including but not limited to needles, scalpel blades, razors, and broken glass.

(23) through (29) remain as proposed.

AUTH: 50-48-103, MCA

IMP: 50-48-102, 50-48-103, MCA

RULE XI (37.112.131) STERILIZATION OF EQUIPMENT AND JEWELRY

(1) remains as proposed.

(2) All jewelry must be sterilized or disinfected by at least one of the following methods:

(a) individually wrapped and autoclaved;

(b) come from the supplier individually wrapped and sterile; or

(c) ~~be sterilized with a liquid chemical sterilant that has been approved for use by the U.S. Food and Drug Administration~~ be disinfected by complete immersion in 70% alcohol.

(3) through (5) remain as proposed.

AUTH: 50-48-103, MCA

IMP: 50-48-103, MCA

RULE XII (37.112.132) CLEANING AND ULTRASONIC USE (1) through (4)

remain as proposed.

~~(5) If the artist uses the ultrasonic unit at the work station to rinse instruments, a single-use cup or single-use liner must be placed in the tank prior to use and changed between clients, unless the tank is autoclaved between clients. The used liner must be disposed of in accordance with [Rule XIV] regarding the disposal of contaminated waste.~~

~~(6)~~ (5) Ultrasonic unit use, cCleaning, dusting, or vacuuming is prohibited during times when clients are being tattooed or pierced.

AUTH: 50-48-103, MCA

IMP: 50-48-103, MCA

RULE XIII (37.112.133) SKIN PREPARATION, ASEPTIC TECHNIQUE, AND AFTERCARE (1) through (3) remain as proposed.

(4) Artists shall wear a clean outer garment. A hair restraint must be worn if necessary to prevent the artist's hair from contact with the client. All necklaces, bracelets, or other personal items of the artist either must be removed or covered by the outer garment or sterile gloves to prevent the item coming in contact with the client.

(5) through (12) remain as proposed.

AUTH: 50-48-103, MCA

IMP: 50-48-103, MCA

RULE XVII (37.112.144) CONSENT FORM (1) The client must sign a consent form before each tattooing or body piercing procedure. If the client is under the age of 18, then the client's parent or legal guardian must sign the consent form, in person, before the procedure.

(2) remains as proposed.

AUTH: 50-48-103, MCA  
IMP: 50-48-103, MCA

RULE XXI (37.112.152) LICENSE FEE AND EXPIRATION (1) Except as provided in (2), ~~The~~ license fee is \$135.

(2) The license fee for establishments that only pierce ear lobes is \$75.

~~(2)~~ (3) The license will expire annually on December 31 following the date of its issuance.

AUTH: 50-48-103, MCA  
IMP: 50-48-103, 50-48-201, MCA

RULE XXIII (37.112.156) REVIEW OF PLANS (1) through (2)(b) remain as proposed.

(c) copies of the client consent form, and client record form, ~~and all applicable aftercare instructions;~~ and

(d) through (4) remain as proposed.

(5) Changes in the client consent form, and client record form, ~~and all applicable aftercare instructions~~ must be submitted to the department or its designee before implementation.

AUTH: 50-48-103, MCA  
IMP: 50-48-103, MCA

5. The department has thoroughly considered all commentary received. The comments received and the department's response to each follow:

COMMENT # 1: A number of commentors expressed concern that the state and local public health agencies should pursue nonlicensed tattoo and/or body piercing establishments to close them down and/or fine them. Included with these concerns, as well, are specific assertions that public health agencies should prohibit the sale and use of in-home piercing kits, and in-home piercing and tattooing.

RESPONSE: The department agrees that state and local public health agencies should take action to enforce compliance with applicable regulations pertaining to tattooing and body piercing establishments, including the requirement that an establishment be licensed. Public health agencies are required, under 50-48-206, MCA, to conduct investigations and inspections of establishments, and county attorneys are required, under 50-48-107, MCA, to prosecute violations of Title 50, chapter 48, MCA, and these rules.

However, Title 50, chapter 48, MCA, applies only to the activities of a body piercing or tattooing "establishment", which is further defined to be either a body piercing or tattooing operation. It is difficult to refine statutory and regulatory authority to the point of clearly specifying where the conduct of citizens would go from being purely personal in nature, which conduct would not be regulated under Title 50, chapter 48, MCA, or these rules, to being a body piercing or tattooing operation. Such decisions

will have to be made by public health agencies and county attorneys, as appropriate, and on a case-by-case basis. As well neither Title 50, chapter 48, MCA, nor these rules prohibit the sale of in-home piercing kits.

COMMENT # 2: A number of commentors assert the department should prohibit suspension piercing, branding, and other radical body modification practices.

RESPONSE: To the extent that such practices are performed by either a tattooing or body piercing establishment, they are subject to the provisions of Title 50, chapter 48, MCA, and these rules. To the extent that such practices are not performed by either a tattooing or body piercing establishment, they are not contemplated by the provisions of Title 50, chapter 48, MCA, and are beyond the scope of these rules.

COMMENT # 3: A number of commentors assert these rules should prohibit the use of nondisposable piercing guns. The commentors express the belief that nondisposable piercing guns are not able to be autoclaved, so are a source of cross-contamination and infection.

RESPONSE: These rules clearly require that the portion of any instruments used for body piercing or tattooing that can come into contact with blood or bodily fluids must be able to be sterilized by autoclave or must come from the supplier as individually wrapped and sterilized, single-use, disposable items. Information available to the department indicates that all types of piercing guns meeting these requirements are equally safe. Therefore, the department disagrees that nondisposable piercing guns, which use sterile, disposable, single-use inserts for each client, are a greater concern for cross-contamination and infection when used in conformity with these rules.

COMMENT # 4: A number of commentors assert that these regulations should set forth more specific requirements related to the quality of tattoo inks, including that the department should prohibit the use of glow-in-the-dark inks.

RESPONSE: Rule XXVIII (37.112.163) requires that tattooists use only colors, dyes, and pigments obtained from reputable suppliers and that pigments or dyes may not be used if they are disapproved of or under recall by the United States Food and Drug Administration or the department. The department has the authority under the Montana Food, Drug, and Cosmetic Act to prohibit the use of any tattoo ink that is unsafe.

It is important to point out that no state or federal agency certifies the quality or safety of tattoo inks, and that many health care professionals question the "safety" of tattoo inks under any circumstances. Therefore, public health agencies are left to evaluate the quality and safety of tattoo inks strictly on the basis of whether or not there is evidence that a specific ink or type of ink poses a significant health or safety risk to those persons injected with it. At this time, the scientific information available to the department does not substantiate that glow-in-the-dark inks pose such a risk.

COMMENT # 5: A commentor suggests that the department should establish a standard protocol for aftercare as a component of these rules.

RESPONSE: Aftercare protocols vary based on the particular tattooing/body piercing procedure provided so each establishment needs to develop appropriate aftercare protocols for the tattooing or body piercing procedures it performs. It is not feasible for the department to establish a standard protocol for aftercare that will suffice for every tattooing or body piercing procedure. In fact, because the department is not in a position to evaluate the adequacy of aftercare instructions, the department is amending Rule XXIII (37.112.156) to remove the requirement that aftercare instructions be submitted to the department for review and approval.

COMMENT # 6: A number of commentors assert that the department should expand these rules to include professional competency standards, including standards related to artistic competency, for tattooists and body piercers. Another commentor suggests that the training requirement should be expanded to require 18 months of training and observation followed by six months of hands on experience prior to working in Montana.

RESPONSE: The provisions of Title 50, chapter 48, MCA, authorize the department to set standards to ensure sanitation and safety in body piercing and tattooing establishments. Consequently, issues of the professional competency of individual tattooists and body piercers, including with respect to artistic competency, are beyond the authorized scope of these rules. Professional competency is typically a matter for professional licensure authorities, and generally falls under the authority of a professional licensure entity within the Department of Labor and Industry. Interest in pursuing professional competency requirements should be pursued with the Department of Labor and Industry.

COMMENT # 7: A number of commentors request that the exemption for ear lobe piercing set forth in Rule XXX (37.112.167) be expanded to include all ear piercing, including piercing of the "trailing edge" of the ear, or ear cartilage. These commentors assert that there is no greater infection risk inherent in piercing of the ear cartilage than in piercing of the ear lobe that would justify application of all of the body-piercing rules to an ear piercer who pierces ear cartilage. They further argue that the rules as currently drafted will result in children having to obtain ear cartilage piercings in body piercing establishments where the atmosphere may not be optimal for young children.

RESPONSE: The department disagrees with the commentors assertions that piercing of ear cartilage carries no greater risk of infection than ear lobe piercing. All medical information available to the department indicates that there is a substantially higher risk of infection in ear cartilage piercing as opposed to ear lobe piercing due to the reduced blood flow in cartilaginous tissues, resulting in a reduced capacity for the body to fight any infectious agent introduced to that area of the body. The department maintains that establishments that provide ear piercing to include piercing of the ear cartilage need to comply with all of the regulations applicable to

body piercing establishments for the protection of their clients' health and safety. The department further responds that nothing in these rules prevents ear piercers who pierce ear cartilage from operating establishments that provide an atmosphere appropriate for clients of young age.

COMMENT # 8: One commentor suggests that the department should insert the actual language of 29 CFR 1910.1030 - the federal Occupational Safety and Health Administration's regulations related to control of exposure of blood-borne pathogens - in these rules. The commentor argues that the federal regulations may not be available to everyone, so these rules should include them in their entirety.

RESPONSE: The department responds that inclusion of the federal regulations in their entirety would be unreasonable due to the volume of the federal regulations. Inclusion of the federal regulations in their entirety would add approximately 32 pages of text to these rules, and would result in a less concise, readable, understandable set of rules. As stated in Rule X (37.112.129), the full text of the federal regulations will be available from the department, so will be available within a very reasonable time to any tattooist or body piercer.

COMMENT # 9: One commentor suggests that consent forms to provide tattoos or body piercings to minors, as required by Rule XVII (37.112.144) should have to be signed by the parent or legal guardian in person.

RESPONSE: The department agrees that the requirement for written consent to provide a tattoo or body piercing to a minor has very little practical value if the consent is not required to be given in person. The department cannot, and does not, expect tattoo and body piercing establishments to verify a written consent where the parent or legal guardian is not personally present to sign a consent form. Further, state law (45-5-623, MCA) currently makes it an "illegal transaction with a minor" to tattoo or body pierce a minor without in person consent of a parent or guardian. Therefore, the department has modified Rule XVII (37.112.144) to require "in person" signing of a parental consent form.

COMMENT # 10: A number of commentors request that the specifics of a training program and the fee to be charged for training, as required in Rule XVIII (37.112.147), be set forth in that rule. Another commentor suggests that the required training should include testing.

RESPONSE: It is not possible for the department to identify the specifics of a training program or the fees to be charged for training. The department will not directly provide the required training, but plans at this time to provide links to training programs offered by qualified, independent entities. The substance of and fees for the training programs, including any testing component, will be those established by the training entities. To the extent that the recommendation for testing may be related to general artist competency, the department refers the commentor to its response to Comment #6.

COMMENT # 11: A number of commentors request that the licensure fee for establishments that perform only ear lobe piercing should be reduced.

RESPONSE: The department agrees that the licensure fee for such establishments should be reduced from the current fee of \$135.00 applicable to other tattooists and body piercers. A reduced fee for establishments that do only ear lobe piercing is reasonable since such establishments will require less time from the department and/or local public health agencies for purposes of plan reviews and inspections. Therefore, the department has modified Rule XXI (37.112.152) to require a licensure fee of \$75.00 for establishments that perform only ear lobe piercing.

The department now estimates that 100 licenses per year will be issued. Of the total number of licenses issued, the department expects to issue about 25 licenses to establishments that only pierce ear lobes, at a cost of \$75 per license, for a total of \$1875. The other 75 licenses will be issued at \$135 per license, for a total of \$10,125. The department also anticipates 120 people will participate in training with the department at \$60 per participant, for a total of \$7200. The total first year revenue will be \$19,200. The expenses for the first year of operation of the licensing program, including database development, rule development, initial training, publication of rules, mailing of rules, and travel, are anticipated to be \$19,200. The net impact to the state's general fund is expected to be \$0.

COMMENT # 12: A number of commentors assert that ear piercing should be exempted from these rules in entirety. They argue that the regulations will put ear piercers out of business and force children to go to body piercing establishments to have their ears pierced, which establishments may subject children to ideas and conditions that are not appropriate for young minds.

RESPONSE: The department disagrees that ear piercers should be totally exempt from application of these rules. First, the definition of "body piercing" in 50-48-102(1), MCA clearly includes ear piercers. Therefore, the department is required to include ear piercers in regulations promulgated under the authority of Title 50, chapter 48, MCA. Second, it is reasonable and appropriate for the department to license and regulate ear piercers to ensure such services are provided in a safe and healthful manner. While the department concedes there are lower risks of infection associated with ear lobe piercing as opposed to other types of body piercing, it believes the exemptions provided in Rule XXX (37.112.167) relieve ear lobe only piercers of the burden of complying with portions of these rules that do not confer significant additional safety or health risk prevention to their clients. As well, the department has reduced the licensure fees applicable to establishments that pierce only ear lobes. The department does not agree that these rules, in total, impose such a burden on such establishments that they will be forced out of business. In fact, the department believes these rules, as applicable to ear piercing establishments, impose a minimal burden that is more than offset by the additional protection provided to their customers.

COMMENT # 13: A commentor suggests that Rule X (37.112.129), which requires

compliance with the blood-borne pathogen exposure control measures set forth in 29 CFR 1910.1030, should be modified to use the terms "standard precaution" and "body substance precaution". The commentor indicates that the federal Occupational Safety and Health Administration has modified its terminology because it is not possible to know, in every circumstance, whether or not a bodily fluid contains blood.

RESPONSE: The department appreciates the commentor's detailed concern and suggestion on this point. However, the department's review indicates that "universal precaution" is still the term defined in federal regulations, and that term is defined and used in the federal regulations broadly enough to include not only blood, but all other bodily fluids that may be infectious for HIV, HBV, and other blood-borne pathogens. The department believes using the additional terms suggested by the commentor would result in unnecessary confusion, and would not result in more comprehensive application of infection control precautions.

COMMENT # 14: A commentor suggests that Rule VI(10) (37.112.116) be amended to specify that handwashing sinks be supplied with liquid soap in single pump dispensers rather than bar soap, as bar soap can harbor bacteria.

RESPONSE: Although bacteria can be found in any type of soap, the department is aware of no scientific evidence that bar soap supports the growth of pathogens. It is the physical action of rubbing hands together with soap and thoroughly rinsing them with clean water that removes dirt and pathogenic microorganisms. In the absence of scientific information establishing that liquid soaps provide additional infection control, the department has no basis for requiring use of a specific type of soap.

COMMENT # 15: A commentor suggests that Rule VII(12) (37.112.117) be amended to also prohibit the application of cosmetics or the inserting or removing of contact lenses in the work area.

RESPONSE: The department responds that if universal precautions are followed, as required by these rules, including adequate handwashing, there is adequate protection for the tattooist or piercer and the client. The department asserts that requiring an artist or client to leave the room to use a public restroom if a contact lens needs to be removed due to a chemical splash or foreign material in the eye is an unnecessary requirement, and potentially less protective of the health and safety of the affected person, when observance of universal precaution requirements following the incident, including handwashing, are sufficient.

COMMENT # 16: A commentor recommends amending Rule XI(2) (37.112.131) to allow disinfection of jewelry with a liquid disinfectant, and to remove the option that jewelry might be sterilized by the use of a liquid chemical sterilant. The commentor points out that a cold sterilant solution is toxic chemical solutions that requires an activating agent and may only be used in conjunction with a very sophisticated air ventilation system. The commentor further points out that most operators are probably using a liquid disinfectant soak for a certain period of time, which measure



is sufficient to sterilize the surface of an article of jewelry.

RESPONSE: The department agrees that the intent of the rule is to allow the use of jewelry that, if not received from the supplier individually packaged and sterile, is either sterilized by autoclaving, or is disinfected by immersion in a liquid disinfecting agent. Therefore, the department has modified Rule XI(2) (37.112.131) to delete the option for chemical sterilization, and to include an option for disinfection by complete immersion in a 70% alcohol solution for at least ten minutes.

COMMENT # 17: A commentor recommends amending Rule XII (37.112.132) to delete the option for using an ultrasonic unit at the work station to rinse instruments. The commentor points out that the use of an ultrasonic unit with its lid open is contrary to manufacturers' instructions for the use of ultrasonic units. More importantly, the commentor also points out that ultrasonic units running with their lids open release microscopic droplets of contaminated water into the air, which poses a health risk to both the artist and the client.

RESPONSE: The department has reviewed this issue and concludes that the commentor is correct. Most importantly, the use of an ultrasonic unit for rinsing instruments while working will result in the release of droplets of contaminated water into the air of the work room. The potential for infection by such use of ultrasonic units far outweighs any convenience to the artist from this method of cleaning instruments. Therefore, the department has amended Rule XII (37.112.132) to prohibit the use of ultrasonic units in the work space at times when clients are being tattooed or pierced.

COMMENT # 18: A commentor recommends that Rule XIII (37.112.133) be amended to require disposal of razors in sharps containers, as razors can carry infectious disease and pose a risk of puncturing or cutting artists or workers if disposed of in wastebaskets.

RESPONSE: The department agrees with the commentor's assertions. While the department initially believed that razors were included in the definition of "sharps" as used in these rules, upon review, the department has determined that the cross-reference to the definition of "sharps" in 75-10-1003, MCA, by the use of the term "health care article" in that definition, is too narrow to include razors, and too narrow to encompass most of the items intended to be defined as "sharps" in these rules. Therefore, the department has revised the definition of sharps in these rules to clearly identify those items that must be disposed of as "sharps" in the context of these rules.

COMMENT # 19: A commentor recommends amending these rules to prohibit the continued use of reusable, acetate stencils. The commentor asserts that such stencils can be a source for transmission of blood-borne pathogens.

RESPONSE: While the department does not disagree that reusable stencils can be a source for transmission of pathogens, that risk is the result of the reusable nature

of the stencils. When properly disinfected, as required by these rules, reusable acetate stencils are safe. Since the risk of use of reusable acetate stencils is easily avoided, the department does not find it necessary to prohibit their continued use.

COMMENT # 20: A number of commentors request that these rules be expanded to prohibit establishments that do ear lobe only piercing from doing other types of piercings.

RESPONSE: The department responds that application of these rules is based on the types of services provided by tattoo and body piercing establishments. If an establishment provides piercing services beyond ear lobe only piercing, including by providing ear cartilage piercing services, the establishment must comply with all of the regulations applicable to body piercing establishments. The department further responds that enforcement efforts under these rules will be commensurate with that requirement. Therefore, the department believes the rules are adequate to prevent ear piercing establishments that provide ear cartilage piercings from operating under the lesser compliance obligations applicable to establishments that perform only ear lobe piercing.

COMMENT # 21: A number of commentors suggest that these rules should specify a minimum age for individuals receiving tattoos or body piercings. They point out that it is currently permissible to tattoo or body pierce a child of any age with parental consent, and that reputable tattooists and body piercers are opposed to providing their services to very young children.

RESPONSE: The department responds that establishing a minimum age for tattooing and body piercing is beyond the scope of the department's authority, and beyond the scope of the authorizing statutes as set forth in Title 50, chapter 48, MCA. The department's charge for rulemaking is to promulgate rules related to the licensure of tattoo and body piercing establishments, and to ensure sanitation and safety in establishments to protect the public health and safety. Since there is no scientific information available to the department that tattooing or body piercing presents a greater health or safety risk to children if appropriate sanitary and safety standards are observed, as required by these rules, it is beyond the department's authority to establish a minimum age limit.

COMMENT # 22: A commentor recommends that Rule XIII (37.112.133) be expanded to require prevention of cross-contamination by an artist's watch, jewelry, or other items that might inadvertently come in contact with the client.

RESPONSE: The department agrees that expansion of this rule would be helpful to identify this additional, commonly present, potential source of cross-contamination. Therefore, the department has modified Rule XIII(4) (37.112.133) to require that all jewelry or other personal accessories worn by an artist must be covered either by the artist's clothing or sterile gloves to prevent contact of the accessory with the client's skin.

COMMENT # 23: A commentor objects to the use of the terms, "sterile", "sterilize", "single-use", etc., in these rules. The commentor asserts that such language is appropriate to operating rooms, but that no items used by tattooists or body piercers are truly sterile and it is unreasonable to expect that sterilization can be achieved in a public business atmosphere.

RESPONSE: The department responds that the rules, as modified and set forth in this notice, accurately use these terms. It is, in fact, possible to sterilize certain appliances and instruments by autoclaving or to purchase sterile, prepackaged materials from suppliers. The department acknowledges that sterilization of jewelry by submersion in liquid sterilants was not the intended standard, as discussed in Comment #16, and that language has been amended to accurately express an acceptable method of disinfecting jewelry. In all other circumstances, the department believes these rules accurately indicate requirements for sterilization and disinfection and represent a necessary and achievable level of sanitary operation for tattoo and body piercing establishments.

COMMENT # 24: A commentor requests that the rules be modified to allow establishments to use up their current supplies of latex gloves. The commentor asserts that establishments typically purchase gloves by the case, and to require an immediate switch to nonlatex gloves would result in financial waste to those establishments who have to throw away their remaining latex gloves.

RESPONSE: The department understands and appreciates the concern expressed by this commentor. However, the department believes the potential health risks to artists and certain clients of tattoo and body piercing establishments by the continued use of latex gloves outweighs the potential cost to tattoo and body piercing establishments incurred in discarding any remaining latex gloves they may have.

COMMENT # 25: A commentor asserts that these rules should be expanded to prevent the sale of tattooing and piercing machines to the general public.

RESPONSE: The department responds that it is beyond the scope of the rulemaking authority conferred on the department by the provisions of Title 50, chapter 48, MCA, to regulate who may or may not purchase such machines or equipment.

COMMENT # 26: A number of commentors request that these rules be modified to suggest or require that a client should see their tattooist or body piercer prior to seeing a doctor when there is redness or swelling at a tattoo or piercing site. The commentors assert that a client will frequently see a doctor immediately when redness or swelling occurs, and that such clients are frequently told by doctors that they have an infection and/or that piercing jewelry needs to be removed. The commentors suggest that, in many such cases there is no infection, but rather just the normal initial swelling and/or redness associated with a tattoo or body piercing procedure. The commentors are concerned that a doctor's indication that there is

infection reflects badly on the tattooist or body piercer's reputation and business, and assert that the tattooist or body piercer can evaluate whether the redness/swelling is a normal reaction, whether the redness/swelling can be resolved by changing to different jewelry, or if the redness/swelling is due to infection that requires medical attention.

RESPONSE: The department responds that it cannot and will not promulgate rules that constitute medical advice, or that may be construed to discourage any person from seeking medical care.

COMMENT # 27: A commentor states that the commentor uses vinyl gloves and not nitro gloves as required under these rules.

RESPONSE: The department points out that nitro gloves are not required under these rules. Rule IX(3) (37.112.125) states that gloves that come into contact with skin must be single-use nonlatex examination gloves designed for medical or clinical use. A tattooist or body piercer could use vinyl gloves if they are nonlatex gloves that otherwise comply with the requirements of this rule.

COMMENT # 28: A commentor expresses concern with the work area requirements and states that the commentor uses a standard contained rolling cart for all of the commentor's piercings.

RESPONSE: It is difficult to discern from the comment provided exactly what the commentor's concerns are related to the work area requirements. The department responds that nothing in these rules would prohibit the use of rolling carts for holding piercing supplies. Assuming the commentor is asserting the rolling cart constitutes a sufficient "work area", and the commentor should not have to comply with all of the work area requirements, the department responds that work area requirements as set forth are minimal, reasonable requirements to ensure that necessary sanitary conditions exist in the locations where body piercings are performed. The department further responds that body piercers who provide only ear lobe piercing are exempt from the requirements of sections (2), (5), and (8) of the work room requirements as set forth in Rule VII (37.112.117). The department is unable to provide any further response to this nonspecific comment.

COMMENT # 29: A commentor expresses concern about the provisions requiring outside ventilation. The commentor asserts that mechanical ventilation needs to be an acceptable option for establishments since the location of some establishments might mean that air brought in from the outside is contaminated by other nearby businesses.

RESPONSE: The department responds that none of the provisions related to ventilation indicate that air must be brought in directly from the exterior of the business location. Rule VI(3) (37.112.116) requires that toilet rooms in establishments be vented to the outside. This requirement does not mean that ventilation must be accomplished by a two-way exchange of air. Rather, this

provision requires only that toilet rooms must be vented to allow the evacuation of air in the toilet room to the exterior of the building. Rule VII(6) (37.112.117) requires that a work room have adequate ventilation, and further requires that if heating ducts, vents, or air conditioners discharge into the work room, the intakes for those mechanisms must be filtered. Again, this provision is clearly concerned with the sufficiency of airflow in the work room and with preventing the introduction of contaminating substances into the work room. Nothing in this provision prevents the use of mechanical ventilation systems.

COMMENT # 30: A commentor objects to the amount of the licensing fee. In general, the commentor asserts that the approximately 350 beauty salons that do ear piercing were not counted when the department set the license fee, so the total fees collected should now be reduced to prevent the department from making a profit on the license fees. Specifically, the commentor asserts that the department should consider reducing the license fee for establishments that provide both tattooing and body piercing services.

RESPONSE: The department responds that beauty salons who provide ear piercing services were considered when determining the appropriate license fee. As well, as discussed in Comment #11, the license fee for establishments that provide only ear lobe piercing services has been reduced to \$75.00. Further, the department finds no justification for the assertion that multi-type establishments - those providing both tattooing and body piercing services - should pay a lower license fee. If the commentor's assumption is that multi-type establishments will pay two license fees, the department responds that the assumption is incorrect. These rules clearly set forth that a license is issued, and a license fee is therefore charged, to an "establishment". An establishment, pursuant to 50-48-102(3), MCA, means either a body piercing operation, a tattooing operation, or a combination of both operations in a multi-type establishment. Therefore, a multi-type establishment will pay only one license fee.

COMMENT # 31: A commentor observes that most piercings become infected by the customer touching it, and asserts that these rules need to emphasize and require that piercers provide appropriate instructions to their clients.

RESPONSE: The department responds that these rules do adequately address the issue of aftercare instructions. Rule XIII(1) (37.112.133) states that appropriate aftercare instructions must be provided to a client both verbally and in writing before every procedure.

COMMENT # 32: A commentor states that no salons were informed of the proposed regulations or that they would be impacted by them. The commentor asserts that the department needs to inform salons of rules that apply to them.

RESPONSE: The department responds that it made every reasonable effort to communicate with all affected parties regarding the proposed rules. The department contacted the Board of Barbers and Cosmetologists to obtain mailing lists.

However, the board was not able to provide mailing lists to the department, and indicated that it would send its own notice of the proposed rules. The board sent the notice indicating that licensure for ear piercing would be required in the future, that rules were being promulgated, and provided contact information for salon operators to contact the department with any questions. The department complied with all applicable laws related to notification of rulemaking and public hearings, including by publication in newspapers of general circulation across the state. Going forward, full communication will be easier since salons providing ear piercing services will be licensed by and known to the department.

COMMENT # 33: A commentor suggests that the department and local public health inspectors should perform unannounced inspections of tattoo and body piercing establishments to better identify noncomplying establishments.

RESPONSE: The department agrees that unannounced inspections are necessary in order to identify noncomplying establishments. The department responds that compliance inspections related to public health statutes and regulations are typically performed by public health inspectors on an unannounced basis. Therefore, inspections performed pursuant to Title 50, chapter 48, MCA, and these rules will typically be performed without prior notice to establishment operators.

/s/ Denise Pizzini  
Rule Reviewer

/s/ Joan Miles  
Director, Public Health and  
Human Services

Certified to the Secretary of State March 12, 2007.